October 2007

Arizona State Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

1700 W Washington St, Room 250, Phoenix, AZ 85007
Web site: *www.azpharmacy.gov*
E-mail: info@azpharmacy.gov

Renewal Process for Licenses and Permits Expiring October 31, 2007

It's that time of year again; the time for Halloween and more importantly the month when approximately 50% of all of the licenses and permits (credentials) issued by the Arizona State Board of Pharmacy require renewal. This year is an odd year so most licenses and permits that are due to renew are also odd numbered. There is a relatively small amount of even-numbered credentials, most of them new, which also are due to renew at this time. The odd-numbered credentials will renew for two years while the even-numbered credentials will (in almost all cases) renew for only one year. This helps the Board maintain an odd/even renewal cycle and results in a steady revenue stream with about 50% of revenues receipted in each year of our two-year budget cycle.

On Thursday, September 13, 2007, the Board office mailed renewal notices to the addresses on file for all credential holders due to renew. The renewal notices provide instructions for the Board's online credential renewal process. The Board hopes that almost all renewals will be processed using the online service. The notice also provides instructions for renewing by mail if you are due to renew and are unable to renew online. You can obtain a "generic" credential renewal form from the Board Web site: *www.azpharmacy.gov.* There are two generic renewal forms, one for licensees and one for permit holders, and both are located under the "Forms" link on the left side of the Web page in the yellow bars section labeled "FIND BY CATEGORY." Please use the credential and fees information provided on the renewal notice you received in the mail to complete the generic renewal form and mail it with your payment to the Board offices located on the second floor of the Executive Tower, Room 250 at 1700 W Washington St, Phoenix, AZ 85007.

Permit Holder May Be Held Responsible for Unprofessional or Unethical Acts of Employees

Recently, the Board concluded that there may be circumstances when it is necessary and appropriate for the Board to discipline or sanction a permit holder for the action(s) of an employee. Arizona Revised Statute (ARS) §32-1927 provides that:

A. The board may discipline a permittee if:
   1. The board determines that the permittee or permittee's employee is guilty of unethical conduct pursuant to section 32-1901.01, subsection A.
   2. Pursuant to a psychiatric examination, the permittee or the permittee's employee is found to be mentally unfit to safely engage in employment duties.
   3. The board determines that the permittee or the permittee's employee is physically or mentally incapacitated to such a degree as to render the permittee or permittee's employee unfit to safely engage in employment duties.
   4. The permit was issued through error.
   5. A permittee or permittee's employee allows a person who does not possess a current license issued by the board to work as a pharmacist, pharmacy intern, graduate intern, pharmacy technician or pharmacy technician trainee.

B. A permittee who after a formal hearing is found by the board to be guilty of unethical conduct, to be mentally or physically unable safely to engage in employment duties or to be in violation of this chapter or a rule adopted under this chapter or whose employee after a formal hearing is found by the board to be guilty of unethical conduct, to be mentally or physically unable safely to engage in employment duties or to be in violation of this chapter or a rule adopted under this chapter is subject to any one or combination of the following:
   1. A civil penalty not to exceed one thousand dollars for each for each violation of this chapter or a rule adopted under this chapter.
   2. A letter of reprimand.
   3. A decree of censure.
   4. Probation.
   5. Suspension or revocation of the permit.

Continued on page 4

Public Hearing Garners Recommendations on Use of Medication Guides

Participants in a public hearing held in June 2007 by the Food and Drug Administration (FDA) Center for Drug Evaluation and Research suggested ways to improve the FDA Medication Guide program. The program provides for the distribution of FDA-approved written patient information for certain medications that pose serious and significant public health concerns.

FDA officials heard testimony from a member of Congress and 40 individuals representing academia, consumers and consumer groups, the pharmaceutical industry, health care professional groups, practicing physicians, pharmacists, and pharmacy organizations.

Participants acknowledged the importance of patients receiving appropriate risk information in the form of Medication Guides to make informed decisions about certain prescribed medications. Some said the current program is too cumbersome and lacks a standard distribution system. Participants urged FDA to increase awareness of Medication Guides, make them easier to read and understand, move toward facilitating electronic distribution, and consider combining the information contained in Medication Guides with other information such as in Consumer Medication Information.

The public hearing is summarized on the FDA Web site at *www.fda.gov/cder/meeting/medication_guides_200706.htm.*

Reporting Makes a Difference

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures and publishes its recommendations. To read about the recommendations for prevention of reported errors that you can put into practice today, subscribe to ***ISMP Medication Safety Alert!® Community/Ambulatory Edition*** *by visiting www.ismp.org. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

In both Institute of Medicine (IOM) reports, *To Err is Human: Building a Safer Health System,* and *Identifying and Preventing Medication Errors,* the importance of error reporting is highlighted. The reports suggest that greater effort is needed to identify medication errors in most care settings, both to measure the extent and scope of errors and to assess the impact of prevention strategies. Although no single recommendation or activity offers a full solution to medical error, error prevention experts agree that successful error reduction strategies depend heavily on responsible detection and open reporting of errors.

According to the IOM report, reporting programs, whether voluntary or mandatory, must satisfy two primary purposes:

1. to hold providers accountable for performance and patient safety; and
2. to provide information that leads to new knowledge and improved patient safety.

Reports to voluntary systems typically come from front-line practitioners or others similarly close to the error, who can best describe the specific conditions that led to that error. Better error descriptions make possible more effective analysis of the system-based causes of errors. This first-hand reporting and the improved analysis it affords has been used by error prevention experts to create a "road map" for improvement that easily and realistically can be extrapolated and implemented at the broadest variety of health care organizations. These practical recommendations for safe practice have been established, published, and widely disseminated throughout the health care community.

Further, voluntary reporting programs have learned that many errors are caused by factors outside the health care practice site and beyond the direct control of a health care practitioner. Thus, safe practice recommendations have been communicated to medical device manufacturers, pharmaceutical companies, automation technology companies, health care reimbursement systems, and others less directly involved in patient care, but nonetheless influential in the safe provision of care.

The success of current voluntary reporting systems also stems from the trust and respect that has typically developed between reporters and recipients who use the information to improve patient safety across the nation. Reporting is perceived to have immense value when those who report an error or potentially hazardous situation can readily see that the information is swiftly acted upon and used confidentially and proactively to develop and publish safe practice recommendations that can prevent errors.

The USP-ISMP Medication Errors Reporting Program (MERP) operated by the United States Pharmacopeia (USP) in cooperation with ISMP is a confidential national voluntary reporting program that provides expert analysis of the system causes of medication errors and disseminates recommendations for prevention. Regulatory agencies and manufacturers are notified of needed changes in products when safety is of concern.

Without reporting, such events may go unrecognized and thus important epidemiological and preventive information would be unavailable. Errors, near-errors, or hazardous conditions may be reported to the program. These include, but are not limited to, administering the wrong drug, strength, or dose of medications; confusion over look-alike/sound-alike drugs; incorrect route of administration; calculation or preparation errors; misuse of medical equipment; and errors in prescribing, transcribing, dispensing, and monitoring of medications.

Providing causative information on actual or potential errors, or near misses to USP and ISMP, which is automatically shared with FDA and the involved manufacturers, has resulted in drug name changes. For example:

- Losec® (error reports indicating mistaken as Lasix®) to Prilosec®,
- Levoxine (error reports indicating mistaken as Lanoxin®) to Levoxyl®,
- Reminyl® (error reports indicating mistaken as Amaryl®) to Razadyne™ (and unfortunately new error reports show Razadyne being mistaken as Rozerem™)

♦ and the most recent, Omacor® (error reports indicating mistaken as Amicar®) to Lovaza.

To those who report medication errors, keep up the great work. The actions resulting in the name changes listed above, alone, demonstrate the tremendous impact you make when you report your experiences to USP-ISMP MERP. Many other error reports have resulted in manufacture label and stock bottle changes. For more information on reporting incidents, visit *www.ismp.org* and click on "Report Errors."

FDA Finds Consumers Still Buying Potentially Risky Medications via Internet

FDA continues to warn the American public about the dangers of buying medications over the Internet.

New data collected by FDA show that consumers who are trying to save money on prescription drugs need not take chances by buying prescription drugs from foreign Internet sites because low-cost generic versions are available in the United States. These findings also indicate that some consumers are likely buying foreign drugs online to avoid having to obtain a prescription from their doctors or health care professionals, as many Web sites do not require a prescription.

FDA urges consumers to obtain prescriptions from their doctors or other health care professionals before using prescription drugs, stating that the use of prescription medications without a prescription is an "intrinsically unsafe practice." FDA also encourages consumers to review *www.fda.gov* for information on buying medications online before making such purchases.

FDA cites the following potential risk factors associated with buying medications from unregulated Internet sellers:

♦ inadequate labeling for safe use;
♦ inappropriate packaging and, therefore, uncertain product integrity;
♦ possible previous withdrawal from the US market for safety or efficacy reasons;
♦ drug-specific risks requiring initial screening and/or periodic patient monitoring;
♦ potential harm or abuse, such as with the use of controlled substances; and
♦ potential drug-drug interactions.

Recent examinations of a sample of drugs shipped to US consumers found several drugs are associated with higher risks if used without the supervision of a doctor or health care professional. For example: the use of warfarin requires close monitoring to prevent stroke or death; amoxicillin and other antibiotics should not be used for self-treatment because of the risk of antibiotic-resistant infections; levothyroxine use requires close monitoring to ensure effective treatment; and clopidogrel may pose increased risk of cardiac events, such as heart attack, if used in suboptimal doses, which might be found in imported tablets.

Improper labeling also presents a risk to consumers. For example, alendronate sodium labeling should warn patients of significant side effects with improper use. In addition, imported eye drop preparations may have been manufactured under unsterile conditions, presenting a risk of contamination that may result in serious infections.

In light of these and other risks associated with medications purchased over the Internet, FDA stresses the importance of obtaining only FDA-approved drugs along with health care provider monitoring.

Death in Canada Tied to Counterfeit Drugs Bought via Internet

Canada's first confirmed death from counterfeit drugs purchased over the Internet reinforces long-stated concerns of the Canadian Pharmacists Association (CPhA), the association states in a recent press release.

A British Columbia coroner's report concludes that pills bought from a fake online pharmacy are to blame for the March death of a Vancouver Island woman. These drugs were later determined to be contaminated with extremely high quantities of metal.

CPhA is calling on Canadian pharmacists to be especially vigilant and discuss these issues with patients when necessary.

Since 1999, NABP, through its Verified Internet Pharmacy Practice Sites™ program, has warned of the dangers of purchasing potentially counterfeit drugs from illegitimate online pharmacies.

FDA Sets Standards for Dietary Supplements

FDA recently issued a final rule requiring current good manufacturing practices (CGMP) for dietary supplements. The rule is intended to ensure that dietary supplements are produced in a quality manner, free of contaminants and impurities, and accurately labeled.

The regulations establish the CGMP needed to ensure quality throughout the manufacturing, packaging, labeling, and storing of dietary supplements. The final rule includes requirements for establishing quality control procedures, designing and constructing manufacturing plants, and testing ingredients and finished products, as well as requirements for record keeping and handling consumer product complaints.

Manufacturers also are required to evaluate the identity, purity, strength, and composition of their dietary supplements. If dietary supplements contain contaminants or lack the dietary ingredient they are represented to contain, FDA would consider those products to be adulterated or misbranded.

FDA also issued an interim final rule that would allow manufacturers to request an exemption to the CGMP requirement for 100% identity testing of specific dietary ingredients used in the processing of dietary supplements. To be eligible for an exemption, the manufacturer must provide sufficient documentation that less frequent testing would still ensure the identity of the dietary ingredients. FDA is soliciting comments from the public on the interim final rule until September 24, 2007. Comments may be addressed to the Division of Dockets Management Branch at *www.fda.gov/dockets/ecomments.*

The final CGMP and the interim final rule became effective on August 24, 2007. The rule has a three-year phase-in for small businesses. Companies with more than 500 employees have until June 2008, companies with fewer than 500 employees have until June 2009, and companies with fewer than 20 employees have until June 2010 to comply with the regulations.

The FDA Web site provides background information at *www.cfsan.fda.gov/~dms/dscgmps7.html* and a fact sheet at *www.cfsan.fda.gov/~dms/dscgmps6.html.*

More information is available on the FDA Unapproved Drugs Web site at *www.fda.gov/cder/drug/unapproved_drugs/default.htm.*

Continued from page 1

The primary function of this *Newsletter* is to serve as a vehicle for providing information about Board statutes and rules. Permit holders should take notice of the statute referenced above and take any action(s) deemed appropriate to reduce the likelihood of any of the circumstances above. Board sanctions could be the result of significant violations. Training programs may need to be instituted to minimize the potential for the activities that could lead to the disciplines listed above.

Schedule II Prescriptions Now Valid for 90 Days from Date of Issue

Effective September 19, 2007, Schedule II controlled substance prescriptions are valid for 90 days instead of the previous 60-day period. See the newest version of ARS §36-2525 (D) for more information.

Disciplinary Actions – Board of Pharmacy (Actions Since July 2007 Newsletter)

Notice: Before making a prescription-dispensing or other decision pursuant to information in this issue, you are encouraged to verify the current condition of a license with the appropriate licensing agency (Board).

Pharmacy Board Actions

Isaacson, Alan (Pharmacist #7599) – Unauthorized Refills. Six months probation, $2,000 fine and 16 hours of continuing education – Effective July 31, 2007.

Likes, Keith (Pharmacist #7450) – Probation terminated. Effective July 26, 2007.

Marek, Andrew (Pharmacist #13113) – Misfilled prescription. Three months probation and $200 fine. Effective July 31, 2007.

Vertrees, Sarah (Technician #3607) – Diversion of controlled substances. Revocation of license stayed and placed on 18-month probation based on the following terms: Treatment Assessment Screening Center program. Effective July 31, 2007.

Disciplinary Actions – Board of Medicine

Alper, Jeffrey (PA 3001) – *Interim Consent Agreement for Practice Limitations (non-disciplinary).* Medical condition limiting health care tasks. Physician assistant (PA) shall not perform health care tasks until PA applies to the Board and receives permission to do so. Effective July 27, 2007.

Everly, Shelley L. (MD 28385) – Unprofessional conduct/boundary violations. License to practice allopathic medicine is surrendered. Effective June 8, 2007.

Groves, Mary E. (MD 30315) – Unprofessional conduct. License surrendered. Effective June 8, 2007.

Hammer, Eli J. (MD 17176 – *Interim Finding of Fact, Conclusions of Law and Order for Summary Suspension of License.* Violation of previous interim order. License to practice allopathic medicine is summarily suspended pending formal hearing. Effective July 13, 2007.

Kidd, William H. (MD 10216) – *Interim Consent Agreement for Practice Limitation (non-disciplinary).* Medical condition limiting ability to practice. Respondent shall not practice clinical medicine or any medicine involving direct patient care and is prohibited from prescribing any form of treatment including prescription medications until permission from the Board is received. Effective July 3, 2007.

Levitt, Keith (MD 26382) – *Interim Consent Agreement for Practice Restriction*. Noncompliance with another state program (WPHP). Respondent shall not practice clinical medicine or any medicine involving direct patient care and is prohibited from prescribing any form of treatment including prescription medications until permission from the Board is received. Effective May 29, 2007.

Morgan, John (MD 25871) – *Interim Consent Agreement for Practice Restrictions*. Failure to comply with MAP program. Respondent shall not practice clinical medicine or any medicine involving direct patient care and is prohibited from prescribing any form of treatment including prescription medications until permission from the Board is received. Effective July 13, 2007.

Normann, Peter James (MD 33254) – *Amended Interim Finding of Fact, Conclusion of Law and Order for Summary Suspension of License.* Respondent deviated from the standard of care/unprofessional conduct. License to practice allopathic medicine is summarily suspended pending formal hearing. Effective July 12, 2007.

Rath, David A. (MD 17545) – Unprofessional conduct. License suspended 12 months; followed by five years probation upon completion of Board-approved treatment program. Effective June 8, 2007.

Roger, Scott (PA 3627) – (non-disciplinary) Five-year probationary term issued. Respondent shall not work in setting geographically separate from supervising physician; shall not have access/keys to sample medication cabinet; shall not prescribe Schedule II or III controlled substances for two years; shall not work more than 40 hours per week. Effective May 23, 2007.

Tillinghast, James (MD 14418) – Failure to comply with terms of MAP program. Respondent's license for practice of allopathic medicine surrendered. Effective June 8, 2007.

The *Arizona State Board of Pharmacy News* is published by the Arizona State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

Hal Wand, RPh - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Larissa Doucette - Editorial Manager